Remarks

I. Status of the Application and Claims

As originally filed, the present application had a total of 10 claims. In previous prosecution, all of the original claims were cancelled and replaced with new claims 11-27. Subsequently, claim 12 was cancelled, leaving claims 11, and 13-27 pending. In the present response, claims 13, 21 and 24 were cancelled and new claims 28-34 were added. Thus, the claims presently pending are 11, 14-20, and 22-23 and 25-34.

II. The Amendments

Claim 11 was amended by incorporating the limitations of previous claim 13 and to indicate that mutations to the *yjgF* open reading frame are only included within the claims to the extent that they result in an increase in the production of L-threonine. Claim 16 was amended to correct a minor problem with antecedent basis pointed out the Examiner, and claim 21 was cancelled and replaced with claim 28. The latter is simply claim 21 rewritten in independent form incorporating all of the limitations of its base claim, *i.e.*, claim 11. Several additional claims that are dependent upon claim 28 were also added which are clearly supported by the claims originally filed and the specification. Support for new claims 33 and 34 may be found on page 22 of the specification, lines 7-10.

Claim 24 has been cancelled without prejudice herein. This was done in response to a rejection made by the Examiner indicating that the term "maximum amount" is indefinite. Applicant does not agree with the Examiner's view but has cancelled the claim to advance prosecution.

None of the amendments that have been made herein add new matter to the application, and their entry is therefore respectfully requested.

III. Claim Objections

On page 3 of the Office Action, the Examiner objects to claim 16 because the use of the word "composition" is inconsistent with its base claim. In response, Applicant has eliminated the word objected to by the Examiner.

On page 14 of the Office Action, the Examiner indicates that claim 21 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form, including all of the limitations of the base claim and any intervening claims. Applicant has complied by rewriting claim 21 as claim 28 with all of the limitations of base claim 11 incorporated.

In light of the amendments described above, Applicant believes that all of the Examiner's objections have been obviated.

The Rejections

I. Rejection of Claims Under 35 USC § 112, Second Paragraph

On pages 3 and 4 of the Office Action, the Examiner maintains a rejection of claim 24 based upon the allegation that the term "maximum amount" is indefinite. Although Applicant does not agree with the Examiner's assessment, the claim has been cancelled for the purpose of furthering the prosecution of the present application. The cancellation of this claim should not be construed as limiting claims under the doctrine of equivalents with respect to the duration that a culture is maintained. In general, Applicant expects that those practicing the present invention will maintain culture for a period of time until a maximum amount of amino acid has been obtained and doing so would fall within the scope of the present claims.

II. Rejection of Claims Under 35 USC § 112, First Paragraph

On pages 4-14 of the Office Action, the Examiner makes several rejections based upon the written description and enablement requirements of patentability. With respect to all of the claims except 17 and 18, the basic argument of the Examiner appears to have two different aspects to it. In the first, the Examiner argues that the term "inactivate" is described in the specification as referring to a loss of activity of the *yjgF* open reading frame rather than as affecting L-threonine production. Given this situation, the Examiner alleges that a mutation that affects the activity of the open reading frame product would be part of the claims, even though the mutation might have no effect whatsoever on amino acid production. Thus, the claims are alleged to fail to meet the enablement and written description requirements.

In response, Applicant has amended the claims so that they now require that the structural changes introduced, *i.e.*, the mutations, result in an increase in L-threonine production. This is essentially the language that is suggested by the Examiner in connection with the enablement rejection made on pages 9-14 of the Office Action. In light of these amendments, Applicant submits that the claims now only encompass mutations increasing L-threonine production and that this aspect of the Examiner's argument has been obviated.

The Examiner also appears to argue that only one way of inactivating the *yjgF* open reading frame has been demonstrated (*i.e.*, deletion of the entire open reading frame) and, as a result, one of skill in the art would not recognize that the inventors were in possession of the many other mutations encompassed by the claims.

Applicant respectfully traverses this rejection.

Applicant does not disagree with the Examiner's statements suggesting that it should be possible to mutate certain amino acids in the *yjgF* open reading frame without affecting the function of the product produced. It is also true that one of skill in the art would not know where such amino acids were *a priori*. Under these circumstances, providing a single example of such a mutation would not suggest where similar mutations could be made and therefore would not support a claim to a genus encompassing many mutated forms of *yjgF*.

However, the present application is dealing with mutations that lead to a <u>*loss*</u> of activity of the gene product. It is true that the production of L-threonine increases, but the activity of the gene itself has clearly been eliminated. This should be apparent from the example provided which demonstrates that the complete deletion of the open reading frame leads to an increase in amino acid production. Unlike the situation described above, this example, *i.e.*, an example leading to a loss of gene activity, immediately makes apparent many other mutations that could be used equally well. For example, given a gene sequence and a method for introducing mutations in the sequence (both of which are clearly taught in the present application), one of skill in the art would recognize that gene function could be disrupted by, *inter alia*: a) introducing a stop codon at a place that prematurely terminates transcription; b) introducing or deleting a nucleotide or two resulting in a frameshift

mutation; or c) replacing all or a portion of the open reading frame with any other unrelated sequence. Thus, when dealing with a loss of activity, a single example demonstrating effectiveness does, in fact, suggest many other examples and supports a claim encompassing an entire genus. In light of this, Applicant submits that for the claims as amended herein, both the written description and enablement requirements of patentability have been met.

With respect to claims 17 and 18, Applicant understands the Examiner's position that, in cases such as the *Univ. California v. Eli Lilly* decision, the Federal Circuit has made it clear that the written description and enablement requirements of patentability, when applied to a claim directed to DNA or a protein, require a structural definition and that claims cannot validly encompass all species of a particular gene or protein. However, these decisions involved cases in which claims were directed to the gene or protein *per se*. That is not the case with respect to claims 17 or 18. The patentability of these claims really depends upon the patentability of claim 11, *i.e.*, it depends upon the novelty and non-obviousness of a fermentation procedure using bacteria with a mutated *yjgF* open reading frame. If such a process is patentable, then it would apply to all bacteria having the stated mutation, regardless of what other genetic manipulations may have been made in the bacteria. Thus, both claims 17 and 18 actually narrow the scope of what is claimed. Under these circumstances, the limitations that are set forth in claims 17 and 18 should be patentable.

Conclusion

In light of the amendments and discussion above, Applicant believes that all of the Examiner's rejections have been overcome. It is therefore respectfully requested that these rejections be withdrawn and that the claims now pending in the application be allowed. Early notice to this effect is earnestly solicited.

If, in the opinion of the Examiner, a phone call would help to expedite the prosecution of this application, the Examiner is invited to call Applicant's undersigned attorney at (202) 419-7013.

Respectfully submitted,

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